REDACTED - PUBLIC VERSION

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-95 (GMS)
CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	REDACTED - PUBLIC VERSION
Defendants.	)	

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS AND TO STRIKE DEFENDANTS' COUNTERCLAIMS AND SEVENTH AFFIRMATIVE DEFENSE

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I. NATURE AND STAGE OF THE PROCEEDING

Genentech filed this patent infringement action on January 12, 2018.[1] On April 16, 2018, Celltrion moved to dismiss or stay it in favor of its own declaratory-judgment action in the Northern District of California, but Celltrion withdrew that motion after the California court dismissed its claims as statutorily barred. *See* D.I. 28; *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-276-JSW, 2018 WL 2448254, at *5-8 (N.D. Cal. May 9, 2018). Celltrion then answered Genentech's complaint in this case and asserted the same declaratory-judgment claims that the California court had dismissed, this time as counterclaims. Genentech now moves to dismiss Celltrion's counterclaims as statutorily barred and, for an inequitable conduct counterclaim and defense, as inadequately pleaded. This is Genentech's opening brief in support of that motion.

II. SUMMARY OF ARGUMENT

This patent dispute arises from Celltrion's efforts to market a biosimilar of Herceptin®, a drug Genentech developed for the treatment of breast cancer. The regulatory approval scheme for biosimilars, contained in the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), sets forth a "carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement" that includes pre-litigation information exchanges and negotiations. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670-71 (2017). This scheme is commonly referred to as the "patent dance." *See id.*; *see also* 42 U.S.C. §§ 262(k)-(*l*).

Celltrion started but did not finish the patent dance. Rather than engage in the statutorily required negotiations to narrow the scope of the infringement litigation, 42 U.S.C. §§ 262(*l*)(4)-(6), Celltrion filed an anticipatory complaint in the Northern District of California

[1] This brief refers to Defendants collectively as "Celltrion," to Plaintiffs collectively as "Genentech," and to individual parties by their full names or by abbreviations defined in the text.

seeking a declaration that 38 of the 40 patents Genentech identified during the parties' exchanges are either invalid or not infringed by its proposed product. *See Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274-JSW (N.D. Cal.). Genentech filed this suit in response and moved to dismiss the California case because the BPCIA bars declaratory-judgment actions by biosimilar applicants that fail to complete their patent dance obligations. The California court agreed and dismissed Celltrion's complaint. *See Celltrion*, 2018 WL 2448254, at *5-8.

Celltrion refuses to give up on its statutorily barred declaratory-judgment claims, now raising them as counterclaims in this case. But they are barred here for the same reasons they were barred in California. Celltrion has purported to take steps over the past two weeks to resurrect the patent dance that it abandoned in January, but a biosimilar applicant cannot quit and then resume the patent dance at its unilateral discretion. And even if it could, Celltrion's recent actions cannot save its counterclaims, because Celltrion missed the BPCIA's deadlines by over four months. Celltrion's counterclaims should therefore be dismissed in their entirety under Federal Rule of Civil Procedure 12(b)(6).

Even if Celltrion's declaratory-judgment counterclaims were not statutorily barred, there are facial pleading deficiencies with Celltrion's assertion that Genentech committed inequitable conduct during prosecution of U.S. Patent No. 6,407,213 (the "'213 Patent") by allegedly misrepresenting the content of the prior art. The Patent Office was fully aware of the references Celltrion cites, and black-letter law holds that a patent owner cannot commit inequitable conduct by making arguments about the references before the examiner that the Patent Office was free to accept or reject. Celltrion's counterclaim VII seeking a declaratory judgment of unenforceability on this basis should therefore be dismissed, and its Seventh Affirmative Defense—which suffers from the same defects as the counterclaim it parrots—should be stricken.

III. STATEMENT OF FACTS

Herceptin® is a genetically engineered antibody that represents a profound breakthrough in the treatment of cancer. After the FDA approved Herceptin®, the scientific community hailed it as "the beginning of a whole new wave of biological drugs that modulate the causes of cancer" and as a sign that "the whole field of cancer research has turned a corner." D.I. 1, ¶ 4. Herceptin® has transformed the treatment of breast cancer and has become the standard of care for its patient population.

Celltrion has submitted an Abbreviated Biologics License Application ("aBLA") seeking FDA approval to market a "biosimilar" of Herceptin® called Herzuma. *See* D.I. 29, Countercl. ¶ 15. A biosimilar is a drug that is similar enough to the innovator product (here, Herceptin®) that the FDA will allow the biosimilar applicant to piggyback on the innovator's clinical trials during the approval process. Celltrion and its marketing partner, Teva, hope to sell their biosimilar to the same patients who would otherwise be prescribed Genentech's Herceptin®. *See* D.I. 1, ¶ 21.

Although the filing of an aBLA is a technical act of patent infringement, the BPCIA directs the parties to engage in a series of exchanges and negotiation before any litigation commences. *See* 35 U.S.C. § 271(e)(2); 42 U.S.C. §§ 262(k)-(*l*); *see also Genentech, Inc. v. Amgen Inc.*, No. 17-1407-GMS, 2018 WL 503253, at *1-2 (D. Del. Jan. 22, 2018). These exchanges, known informally as the "patent dance," are designed to narrow disputes over infringement, in part by ensuring the "reference product sponsor" (here, Genentech) has received enough information from the biosimilar applicant to be able to narrow the patents to be asserted before filing suit. *See Sandoz*, 137 S. Ct. at 1670-71. The exchanges are governed by a series of statutory subsections in 42 U.S.C. § 262(*l*).

After the FDA accepted Celltrion's aBLA for filing on July 28, 2017, Genentech and Celltrion began the patent dance in an effort to narrow the patents that would be at issue in the litigation everyone knew was coming. D.I. 29, Countercl. ¶ 17. Pursuant to 42 U.S.C. § 262(*l*)(3)(A), on October 10, 2017, Genentech served a list of 40 patents that it believed could reasonably be asserted if Celltrion made, used, imported, or offered to sell Herzuma in the United States ("Genentech's 3A List"). *See id.* ¶ 19; Ex. 1.[2] Celltrion continued to participate in the patent dance and served its response under § 262(*l*)(3)(B)(ii) on November 7, 2017 ("Celltrion's 3B Statement"). *See* D.I. 29, Countercl. ¶ 59; Ex. 2. [redacted] *See* Ex. 2 at 1. As to the remaining 38 patents, Celltrion provided non-infringement, invalidity, or unenforceability contentions. *See* D.I. 1, ¶ 33. Genentech provided responsive contentions on January 5, 2018, pursuant to § 262(*l*)(3)(C) ("Genentech's 3C Statement"), narrowing its focus to 18 of the original 40 patents based on representations in Celltrion's 3B Statement about, for example, Celltrion's manufacturing processes. *See* D.I. 29, Countercl. ¶ 62; Ex. 3.

With its 3C Statement, Genentech also started the negotiations required by § 262(*l*)(4) about the scope of the infringement case to be filed by Genentech. *See* D.I. 29, Countercl. ¶ 63. Genentech proposed that the parties litigate the 18 patents for which it provided contentions with its 3C Statement. *See id.*; Ex. 3. Celltrion responded on January 11, 2018, expressing its desire to litigate all 40 patents on Genentech's 3A List.[3] *See* D.I. 29, Countercl. ¶ 64; Ex. 4. [redacted]

[2] "Ex." refers to the exhibits to the Declaration of Andrew J. Danford filed with this brief.

[3] Celltrion appears to take no position on the date the parties' negotiations under § 262(*l*)(4) began, but it alleges that they began no later than January 11, 2018. *See* D.I. 29, Countercl. ¶ 64

[redacted]

Because Genentech and Celltrion had different ideas about the proper scope of a first-phase patent case, the BPCIA contemplated that they would continue to "engage in good faith negotiations." 42 U.S.C. § 262(*l*)(4)(A). But "[i]f, within 15 days of beginning negotiations," Genentech and Celltrion still could not agree, the BPCIA held that "the provisions of [§ 262(*l*)(5)] shall apply to the parties." *Id.* § 262(*l*)(4)(B). Section 262(*l*)(5) provides for an exchange of patent lists to determine the scope of the immediate infringement action. *Id.*

Celltrion did not engage in those good-faith negotiations. Instead, it filed a lawsuit in the U.S. District Court for the Northern District of California seeking declaratory judgment of non-infringement and/or invalidity for each of the 38 patents addressed in its 3B Statement, a mere 20 minutes after making its opening offer. *See* D.I. 1, *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274-JSW (N.D. Cal. filed Jan. 11, 2018).

Celltrion plainly had abandoned the patent dance. So, the next day, Genentech filed this case alleging infringement of all 40 of the patents on Genentech's 3A List. D.I. 1. Genentech filed suit here, because this Court was already presiding over litigation between Genentech and two other companies about the validity and scope of many of the same patents at issue in this case.[4]

("On January 11, 2018, Celltrion, Inc. wrote to Genentech in response to its 3(C) Statement. Celltrion, Inc. stated that, pursuant to 42 U.S.C. § 262(l)(4)(A), Celltrion, Inc. wished to litigate all of the patents on Genentech's 3(A) List.").

[4] *See Genentech, Inc. v. Amgen, Inc.*, No. 17-1407-GMS (D. Del.) (involving claims against Amgen's biosimilar version of Genentech's Avastin® biologic drug); *Genentech, Inc. v. Amgen, Inc.*, No. 17-1471-GMS (D. Del.) (same); *Genentech, Inc. v. Pfizer Inc.*, No. 17-1672-GMS (D. Del.) (involving claims against Pfizer's biosimilar version of Herceptin®).

Genentech moved to dismiss Celltrion's California complaint[5] because, among other things, Celltrion's failure to complete the patent dance caused its declaratory-judgment action to be statutorily prohibited by the BPCIA. *See* 42 U.S.C. § 262(*l*)(9)(B). The California court agreed and, on May 9, 2018, dismissed Celltrion's complaint because "Celltrion was obligated to complete all required procedures [under the patent dance] before filing this lawsuit, and it did not." *Celltrion*, 2018 WL 2448254 at *7. The court rejected Celltrion's arguments that it had complied with the statute. *Id.* at *5-8. The court also allowed Celltrion "leave to amend, to the extent that the identified deficiencies can be corrected consistent with counsels' obligations under Federal Rule of Civil Procedure 11," *id.*, but Celltrion filed a notice that it would not do so. Ex. 5. Final judgment was entered on June 11, 2018. Ex. 6.

Celltrion moved to dismiss this case in favor of the California case, but withdrew that motion when the California case was dismissed. D.I. 28. At the same time Celltrion withdrew its motion, it filed an answer and counterclaims seeking declaratory judgments of non-infringement, invalidity, or unenforceability for 38 of the 40 patents at issue in this case. D.I. 29. Celltrion's counterclaims are virtually identical to the declaratory-judgment claims that the California court dismissed as statutorily barred. *See* Ex. 7 (redline comparing substantive portions of D.I. 29, Counterclaims, to substantive portions of Celltrion's California complaint, D.I. 39-5, *Celltrion, Inc. v. Genentech, Inc.*, C.A. No. 4:18-cv-274-JSW (N.D. Cal. filed Feb. 8, 2018)).

[5] Celltrion filed an amended complaint in California shortly after filing its initial complaint. *See* D.I. 39-5, *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274-JSW (N.D. Cal. filed Feb. 8, 2018). For simplicity, this brief refers to Celltrion's first amended complaint as its complaint.

IV. ARGUMENT

A. Legal Standard

"To survive a motion to dismiss" under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Rule 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law," including lack of a statutory remedy. *See Seismic Reservoir 2020, Inc. v. Paulsson*, 785 F.3d 330, 335 (9th Cir. 2015); *see also Neitzke v. Williams*, 490 U.S. 319, 326 (1989) (holding that "a claim must be dismissed" if "as a matter of law it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations"); *Eisai Co., Ltd. v. Mutual Pharm. Co., Inc.*, No. 06-3613-HAA, 2007 WL 4556958, at *8-12 (D.N.J. Dec. 20, 2007) (dismissing claim under Rule 12(b)(6) for failure to comply with the Hatch-Waxman Act).

Federal Rule of Civil Procedure 12(f) authorizes the Court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Facts underlying a defense must be construed in favor of the nonmoving party, but the Court "is not required to accept affirmative defenses that are mere bare bones conclusory allegations, and may strike such inadequately pleaded defenses." *Sun Microsystems, Inc. v. Versata Enters., Inc.*, 630 F. Supp. 2d 395, 408 (D. Del. 2009) (internal quotations omitted).

B. Celltrion's declaratory-judgment counterclaims are barred by the BPCIA because Celltrion did not complete required steps in the patent dance.

This is the second action in which Celltrion has sought a declaratory judgment of non-infringement, invalidity, or unenforceability of the patents-in-suit. Celltrion first asserted these claims in the Northern District of California, but the California court dismissed them last month

as statutorily barred by the BPCIA because Celltrion had failed to comply with the BPCIA's patent dance procedure. Celltrion repudiated the patent dance when it filed its California complaint in January; it cannot undo that repudiation now. And even if it could, because the time limits for Celltrion to act under the BPCIA expired long ago, Celltrion cannot remedy the deficiencies that plagued its California claims. Each of Celltrion's declaratory-judgment counterclaims (i.e., counterclaims I-LXV) should, therefore be dismissed for failure to state a claim under Rule 12(b)(6).

1. ***The BPCIA establishes a system of incentives and penalties to narrow the scope of biosimilar patent litigation.***

The BPCIA embodies a compromise. Biosimilar manufacturers are spared the tremendous expense of replicating the clinical trials that innovator companies must conduct to obtain regulatory approval. In return, the innovator companies obtain early, pre-litigation access to information needed to identify and narrow patent disputes, and some control over the timing and location of that litigation. As the Supreme Court summarized it last year, the BPCIA "sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Sandoz*, 137 S. Ct. at 1670.

"To encourage parties to comply with its procedural requirements, the BPCIA includes various consequences for failing to do so." *Id.* at 1672. Section 262(*l*)(9) ensures that litigation will be orderly by restricting a biosimilar applicant's ability to bring claims outside the BPCIA framework. For example, to encourage the biosimilar applicant to start the patent dance, the applicant forfeits any right to seek declaratory relief unless it produces its aBLA and the other manufacturing information required by Section 262(*l*)(2)(A). *See* 42 U.S.C. § 262(*l*)(9)(C); *see also Sandoz*, 137 S. Ct. at 1672.

If the biosimilar applicant makes the disclosures required under Section 262(*l*)(2)(A), the BPCIA directs the parties to undertake the series of exchanges contemplated by the patent dance, culminating with an infringement complaint filed by the reference product sponsor (here, Genentech). This is the "first phase" of litigation under the BPCIA. *See Sandoz*, 137 S. Ct. at 1671-72. As an incentive to keep the patent dance exchanges on track, the BPCIA strips the biosimilar applicant of the ability to seek a declaratory judgment for any patent included on the initial list of relevant patents provided by the reference product sponsor (i.e., the sponsor's 3A List) if the applicant fails to complete certain steps of the patent dance. *See* 42 U.S.C. § 262(*l*)(9)(B) ("If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action . . . for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A) . . . ."); *see also Sandoz*, 137 S. Ct. at 1672.

2. *Celltrion's counterclaims are barred by 42 U.S.C. § 262(l)(9)(B) because Celltrion did not complete the patent dance.*

Celltrion's counterclaims for declaratory relief are barred under Section 262(*l*)(9)(B) because Celltrion did not complete the patent dance. Once Genentech served its 3C Statement on January 5, 2018, the BPCIA required Celltrion to initiate "good faith negotiations" over the scope of the first phase of litigation. *See* 42 U.S.C. § 262(*l*)(4)(A); *Celltrion*, 2018 WL 2448254, at *2 ("Following the exchange of the 3(A), (B), and (C) Disclosures, the applicant and the reference product sponsor must engage in 'good faith negotiations' to reach an agreement identifying which patents will be the subject of 'immediate' patent infringement litigation."). If the parties had agreed on a list of patents, Genentech would have been required to "bring an action for patent infringement with respect to each such patent." 42 U.S.C. §§ 262(*l*)(4)(A),

(6)(A). But if the parties could not reach agreement within 15 days of beginning negotiations, "the express terms of the BPCIA required both Celltrion and Genentech to complete the steps outlined in Section (*l*)(5)." *Celltrion*, 2018 WL 2448254, at *5; 42 U.S.C. § 262(*l*)(4)(B). Section 262(*l*)(5) required Celltrion to select and notify Genentech of "the number of patents" to be litigated (i.e., its "5A Number"), *id.* at *2, *5; 42 U.S.C. § 262(*l*)(5)(A), and, within five days of that notice, exchange lists of "Phase I" patents with Genentech (i.e., its "5B List"), *id.* 42 U.S.C. § 262(*l*)(5)(B)(i).

That is how the process should have unfolded. But after receiving Genentech's contentions and opening offer, Celltrion refused to negotiate. Celltrion sent a counteroffer and filed a complaint in California the same day. *Celltrion*, 2018 WL 2448254, at *3; Ex. 4.

The California court concluded that Celltrion's claims were barred by § 262(*l*)(9)(B) "[b]ecause Celltrion did not complete its obligations under Section (*l*)(5)." *Celltrion*, 2018 WL 2448254, at *5. "Celltrion fail[ed] to allege . . . that it provided Genentech with its 5(A) Number or simultaneously exchanged 5(B) lists with Genentech." *Id.* "In these circumstances," the court held, "the BPCIA is clear: Celltrion may not bring a declaratory-judgment action with respect to any patent on Genentech's [3A List]." *Id.* The court then dismissed Celltrion's complaint for failure to state a claim. *Id.* at *8.

Celltrion's counterclaims in this case include virtually the same factual allegations, counts, and requests for relief as Celltrion's California complaint. Exhibit 7 is a redline comparison of the substantive elements of Celltrion's counterclaims in this case against the substantive elements of Celltrion's California complaint.[6] There are no material differences.

[6] To facilitate this comparison, Exhibit 7 omits non-substantive sections, like the introduction, description of the parties, jurisdiction and venue allegations, and description of the statutory scheme. Genentech does not believe these sections are relevant to this motion; but, for

Both pleadings seek declaratory judgments of invalidity, non-infringement, or unenforceability of 38 patents; both assert 65 counts (with the same titles and in the same order); and both include a substantively identical description of the parties' patent dance. And—significantly for this motion—"Celltrion never alleges," in either complaint, "that it either (i) sent its 5(A) Number to Genentech, or (ii) that the parties simultaneously exchanged 5(B) lists" during the patent dance. *Celltrion*, 2018 WL 2448254, at *5. That was dispositive of Celltrion's claims for declaratory relief in California, and it should be dispositive of Celltrion's claims for declaratory relief here.

The only difference between Celltrion's now-dismissed California claims and its counterclaims here is the type of pleading in which they were raised. That is immaterial. As the Supreme Court explained, the BPCIA's declaratory-judgment bars are intended to "encourage parties to comply with [the BPCIA's] procedural requirements" and to provide "consequences for failing to do so." *Sandoz*, 137 S. Ct. at 1672. If a biosimilar applicant starts but refuses to finish the patent dance, one of those consequences is that "the [reference product sponsor], but not the applicant, [may] seek declaratory relief with respect to infringement, validity, or enforceability" of the patents on the sponsor's 3A List. *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1322 (Fed. Cir. 2017). Celltrion's counterclaims seek the same declaratory relief as its California complaint, so Celltrion's counterclaims should be deemed statutorily barred and dismissed.

Any other outcome would allow Celltrion to have its cake and eat it too. If counterclaims are not subject to the BPCIA's declaratory-judgment bars, a biosimilar applicant could engage in the patent dance through the contention exchanges (i.e., the 3B and 3C Statements), abandon the dance, and still exercise the unilateral ability to increase the scope of the infringement action

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completeness, Exhibit 8 is a comparison of Celltrion's entire counterclaims against its entire complaint in the California Action.

through declaratory-judgment counterclaims after it is sued. But the right to exercise some control over the scope of the infringement action is one that a biosimilar applicant earns by complying with the patent dance (e.g., § 262(*l*)(5)(A) allows the applicant to name the number of patents for the first-phase infringement action). Celltrion is attempting to exercise that right without having earned it.

Celltrion will no doubt argue that it should be allowed to maintain its counterclaims so it can get certainty on both infringement and validity of all of the patents on Genentech's 3A List before it launches Herzuma, even if Genentech does not elect to pursue all of those patents through judgment. In a typical patent case, that argument may have merit. *See, e.g.*, 6 Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1406 (3d ed. Apr. 2018 update) (noting that standard practice allows declaratory-judgment counterclaims in infringement cases). But this is not a typical patent case—it is part of Congress's "carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement" for biosimilar drugs. *Sandoz*, 137 S. Ct. at 1670. The BPCIA's declaratory-judgment bars can only be effective at "reinforc[ing] the applicant's incentives to complete the orderly process" set out in the scheme if they have teeth. *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1057 (Fed. Cir. 2016). Celltrion knowingly and willfully abandoned the patent dance, creating litigation on opposite coasts, increasing the costs for the parties, and delaying resolution of this dispute. Section 262(*l*)(9)(B) prescribes the penalty for Celltrion's gamesmanship, and—as the California court has already found—it is the loss of Celltrion's ability to seek declaratory relief.

3. *Celltrion's attempt to resurrect the patent dance after abandoning it for over four months cannot save its statutorily barred declaratory-judgment counterclaims.*

Celltrion attempted to resurrect the patent dance after filing its counterclaims in this case, presumably in an effort to cure the deficiencies that doomed its California claims. On June 6,

2018, Celltrion sent Genentech a letter purporting to contain its 5A Number. Five days later, Celltrion wrote to Genentech again, this time purporting to send its 5B List. Genentech objected to Celltrion's belated attempt to resurrect the patent dance and recapture statutory benefits that it had long ago forfeited by failing to meet the BPCIA's deadlines; but, out of an abundance of caution, Genentech also provided its own list (mirroring its claims in this case).

As a threshold matter, the Court need not address these developments because they are not pleaded in Celltrion's counterclaims. "To overcome a motion to dismiss, the defendant's counterclaim must plead 'enough factual matter that, when taken as true, states a claim to relief that is plausible on its face.'" *EMC Corp. v. Zerto, Inc.*, No. 12-956-GMS, 2014 WL 3809365, at *1 (D. Del. July 31, 2014) (quoting *In re Bill of Lading Transm'n & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1331 (Fed. Cir. 2012) (other internal quotations omitted)). Because Celltrion's counterclaims include only the factual allegations that the California court has already deemed insufficient to state a claim, the Court should dismiss them.[7]

These late-breaking developments, however, fail to save Celltrion's counterclaims. By the time Celltrion purported to provide its 5A Number, at least 146 days had passed since the parties started their negotiations under 42 U.S.C. § 262(*l*)(4). That is far more than the 15 days contemplated by the statute, 42 U.S.C. § 262(*l*)(4)(B), which expired no later than January 26, 2018.[8] As the California court explained, "[a]t th[at] juncture, the express terms of the BPCIA required both Celltrion and Genentech to complete the steps outlined in Section (*l*)(5)." *Celltrion*, 2018 WL 2448254, at *5. But Celltrion did not complete those steps at that juncture.

[7] Even if Celltrion were to amend its pleadings to include its recent attempt to resurrect the patent dance, its counterclaims would still be barred for the reasons discussed in the remainder of this section.

[8] This assumes the parties' § 262(*l*)(4) negotiations began on January 11, 2018, a date that Celltrion alleges they were ongoing. D.I. 29, Countercl. ¶ 64. Genentech maintains that the negotiations began on January 5, 2018, which would create a 152-day gap.

Celltrion permanently abandoned the patent dance in January, and it cannot resurrect it by attempting to cure its failure to act retroactively, let alone over four months later.

The BPCIA does not contemplate an indefinite gap between the parties' negotiations under § 262(*l*)(4) and the list-exchange procedures in § 262(*l*)(5). Section 262(*l*)(4) establishes a clear window for the parties' negotiations: "If, ***within 15 days of beginning negotiations***[, the parties] fail to agree on a final and complete list of [patents for the first-phase infringement suit], the provisions of ***paragraph (5) shall apply*** to the parties." 42 U.S.C. § 262(*l*)(4)(B) (emphasis added). Section 262(*l*)(5)(A) follows with its own command: "The subsection (k) applicant ***shall notify*** the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I)." Nothing in these mandatory provisions contemplates a months-long hiatus.[9]

It is a bedrock principle of statutory interpretation that courts "should favor an interpretation that gives meaning to each statutory provision." *Life Techs. Corp. v. Promega Corp.*, 137 S. Ct. 734, 740 (2017); *see also Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1654 (2017) (noting that under the "surplusage canon," there is a "presumption that each word Congress uses is there for a reason"). But any reading of the BPCIA that would allow Celltrion to resurrect the patent dance months after abandoning the parties' § 262(*l*)(4) negotiations would render the 15-day window in § 262(*l*)(4)(B) meaningless. Parties would be free to drag out the negotiations as long as they would like, effectively stalling the "orderly process" that Congress created. *Amgen*, 827 F.3d at 1057. To avoid distorting the BPCIA's text

[9] Celltrion's own actions signal its lack of faith in this theory. Despite being given leave to amend the complaint in its favored forum (California) "to the extent that the identified deficiencies can be corrected consistent with counsels' obligations under Federal Rule of Civil Procedure 11," *Celltrion*, 2018 WL 2448254 at *8, Celltrion filed a notice that it would not amend on June 8—***two days after*** purporting to reopen the patent dance. *See* Ex. 5.

and frustrating its goals, Celltrion's belated attempt to excuse its noncompliance should be rejected and its counterclaims should be dismissed.

C. Celltrion's counterclaim for a declaratory judgment of unenforceability of the '213 Patent should be dismissed and its related affirmative defense stricken because Celltrion fails to plead a viable theory of inequitable conduct.

Celltrion's counterclaim VII seeks a declaration that the '213 Patent is unenforceable for inequitable conduct.[10] D.I. 29, Countercl. ¶¶ 105-20 (Count VII); *see also id.* at 44 (Seventh Affirmative Defense asserting equitable estoppel, unclean hands, and/or inequitable conduct). Even assuming the Celltrion's counterclaims survive the BCPIA's declaratory-judgment bar, Celltrion has not pleaded sufficient facts to support this claim. It should therefore be dismissed under Rule 12(b)(6) and Celltrion's corresponding Affirmative Defense Seven should be stricken under Rule 12(f).

Unlike the typical inequitable conduct case, *see, e.g.*, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (*en banc*), Celltrion does not allege that Genentech deliberately concealed references in its possession from the Patent Office. To the contrary, Celltrion acknowledges that the Patent Office had and explicitly considered the two identified references—"Queen 1989" and the "'101 patent," D.I. 29, Countercl. ¶¶ 107-08—the Examiner having cited each of them as the basis for rejections during prosecution, *id.* ¶¶ 109-13. Celltrion's theory challenges Genentech's arguments about what these references teach. *Id.* ¶¶ 115-17.

[10] Genentech has moved to dismiss Amgen's virtually identical counterclaim for the '213 Patent in a related case before this Court. *See* D.I. 118, at 11-13, *Genentech, Inc. v. Amgen Inc.*, No. 17-1407-GMS (D. Del. filed May 30, 2018) (redacted version); *see also id.*, D.I. 109, (filed May 22, 2018) (unredacted version).

This is a legally inadequate allegation of inequitable conduct. The Federal Circuit has held repeatedly that a patent applicant's characterizations of the prior art cannot as a matter of law give rise to inequitable conduct where the Examiner could review the reference and was able to consider the argument and accept or reject it. *See, e.g.*, *Rothman v. Target Corp.*, 556 F.3d 1310, 1329 (Fed. Cir. 2009); *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007). "While the law prohibits genuine misrepresentations of material fact, a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct." *Rothman*, 556 F.3d at 1328-29. This makes sense because the Examiner has the underlying references and the "discretion to reject or accept an applicant's arguments based on the examiner's own conclusions regarding the prosecution record." *Id.* at 1329; *see also Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986) (noting that the "examiner was free to reach his own conclusion regarding the Blades process based on the art in front of him"). In *Innogenetics, N.V. v. Abbott Laboratories*, noting that "our precedent has made clear that an applicant is free to advocate its interpretation of its claims and the teachings of prior art," the Federal Circuit affirmed a summary judgment of no inequitable conduct and an award of attorneys' fees incurred in defending the charge. 512 F.3d 1363, 1379 (Fed. Cir. 2008). Trial courts, including in this District, routinely dismiss or reject as a matter of law allegations that an applicant committed inequitable conduct by misrepresenting a reference before the Examiner:

> The court appreciates Precision's position that Shier and Paques expressly contradicted the teachings of Arnould. Precision does not cite authority demonstrating that this fact may substitute for independent evidence of intent to deceive, however, where the prior art at issue was a focus of the examination. Here, both examiners were free to credit or discount Shier and Paques' characterizations of Arnould in view of their own readings.

Cellectis S.A. v. Precision Biosciences, 883 F. Supp. 2d 526, 535 (D. Del. 2012); *see also Bayer Schering Pharma AG v. Barr Labs., Inc.*, No. 05-cv-2308 (PGS), 2008 WL 628592, at *49-50 (D.N.J. Mar. 3, 2008); *Sepracor Inc. v. Teva Pharm. USA, Inc.*, No. 09-cv-01302 (DMC)(MF), 2010 WL 2326262, at *6 (D.N.J. June 7, 2010).

Celltrion's allegation of inequitable conduct should be dismissed for the same reason. Celltrion accuses Genentech of mischaracterizing the antibody numbering methodology in the "'101 patent," "falsely distinguishing" the "Queen 1989" reference, and submitting an allegedly misleading comparison of Queen 1989 to the claimed sequences. D.I. 29, Countercl. ¶¶ 107-08, 113-17. In all these instances, the art was disclosed to and considered at length by the Examiner, who was free to reach his own contrary conclusion. An allegation of inequitable conduct cannot survive that acknowledged fact.

Celltrion's equitable estoppel and unclean hands affirmative defenses suffer from the same defect. These defenses and inequitable conduct "rise or fall together" when based on the same allegations. *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013); *see also Meds. Co. v. Teva Parenteral Meds., Inc.*, No. 09-750-ER, 2011 WL 13135647, at *5-6, *22-23 (D. Del. Aug. 26, 2011). This 40-patent case is complicated enough without injecting Celltrion's unfounded and legally impermissible theories of prosecution misconduct. Count VII in Celltrion's counterclaims should therefore be dismissed with prejudice and Celltrion's corresponding Affirmative Defense Seven should be stricken.

V. CONCLUSION

Genentech respectfully requests that the Court dismiss each of Celltrion's Counterclaims and strike Celltrion's Seventh Affirmative Defense.

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